

FILED: JANUARY 2002
SUPPLEMENTAL PRELIMINARY AMENDMENT

Sub B2

30. The dosage formulation of claim 26 wherein the antibodies bind to the alpha subunit of the Shiga like toxin II.

31. The dosage formulation of claim 26 wherein the antibodies are effective to prevent neurological signs of hemolytic uremic syndrome or lesions.

32. The dosage formulation of claim 26 wherein the antibodies are effective to prolong survival.

33. The dosage formulation of claim 26 in a pharmaceutically acceptable carrier for injection.

34. The dosage formulation of claim 26 equivalent to 4 ml serum from an animal immunized with Shiga-like toxin II/kg body weight.

35. The dosage formulation of claim 26 producing a serum level of anti-Shiga toxin II antibodies of at least about 0.5 micrograms/ml.

36. The dosage formulation of claim 26 equivalent to a dosage of 3 mg human monoclonal antibody to Shiga-like toxin II administered to a newborn pig.

Sub B3

Remarks

The undersigned, the applicants and licensee, Collegium Pharmaceuticals, greatly appreciated the examiner taking the time and extending the courtesy of an interview. To briefly summarize, Mike Heffernan presented on behalf of Collegium, a summary of the issues in the marketplace, the need for this invention, and why Collegium felt it should license this technology. He also explained that Collegium is putting a great of money into the technology and plans to be in clinical trials within a year, if all goes well. As Mr. Heffernan and the inventor, Dr. Saul Tzipori, explained, the prior art recognized that hemolytic uremic syndrome ("HUS") is a major problem, that it is caused by bacterial